

## REMARKS

### I. STATUS OF THE CLAIMS

Claims 1, 5, 8-10, 12-29, 31-40, 44-49, 51-56, 58-62, 66-86 and 88-91 are pending.

Claims 2-4, 6, 7, 11, 30, 41-43, 50, 57, 63-65 and 87 were previously canceled without prejudice against their reintroduction into this or one or more timely filed continuation, divisional or continuation-in-part applications.

Claims 5, 19-40, 44-62 and 66-91 have been withdrawn from consideration as being drawn to non-elected embodiments.

With this Amendment, claims 1, 5 and 23 are amended. Thus, after entry of this Amendment, claims 1, 5, 8-10, 12-29, 31-40, 44-49, 51-56, 58-62, 66-86 and 88-91 remain pending, with claims 1, 8-10 and 12-18 currently under consideration. The amendments of the claims and the various rejections raised in the Office Action are discussed in more detail, below.

### II. AMENDMENTS

Claim 1 is amended to remove the phrase "a non-essential region or."

Claim 5 is amended for proper dependency.

Claim 23 is amended to remove reference to the ORFs of genes 7, 46, 48 and 66.

No new matter is added by way of the amendments presented herein.

### III. CLAIM REJECTION UNDER 35 USC §112

Claims 1, 8-10 and 12-18 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment of Claim 1 to delete the first reference to "a non-essential region" is believed to obviate this rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

### IV. CLAIM REJECTION UNDER 35 USC §103

Claims 1, 8-10 and 12-18 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Horsburgh *et al.* (US Patent 6,277,621 B I, hereinafter, "Horsburgh") in view of Cohen *et al.* (PNAS USA, 1993,90:7376-7380, hereinafter, "Cohen") and Mori *et al.* (US Patent Application Publication 20080226677, filed May 12,2004, hereinafter, "Mori").

Horsbergh describes recombination "in the ORF region" of the gene, and does not disclose or relate to insertion of the BAC sequence into the flanking region of a non-essential

gene. Mori is cited for its teaching of “the use of BAC vectors to express viral genes, as well as the use of recombinant protein dependent recombinant sequences” and the Examiner states that the skilled artisan “would have been motivated to use such sequences in order to control the site of recombination.” (Office Action at page 5). Cohen is cited in attempt to cure the deficiencies of Horsburgh and Mori, for its teaching of inserting a BAC sequence into the non-essential gene region of ORF13. In contrast, the BAC sequence of the present claims is inserted into the region flanking ORF 13.

Moreover, Cohen is irrelevant to the present claims, as Cohen is directed to the production of an ORF13-deficient virus, disrupting its function with the purpose of analyzing the function of ORF13. One of the advantages of the presently claimed subject matter is that using the region flanking a non-essential gene *avoids* disruption of the function of the region into which the BAC vector is inserted (*i.e.* gene 13 following insertion maintains its function).

Thus, Applicants recognized that inserting BAC sequences into the flanking regions allows the cloning of a full length genome without deleting an ORF or function, while avoiding any adverse effects upon viral reconstitution by BAC sequence insertion, even though the BAC sequence insertion may have adverse effects on expression of genes around the insertion region.

The Examiner’s assertion appears to be solely based on hindsight recognition of Applicants’ own disclosure. No reasoning has been provided for how or why the skilled artisan would have chosen, of all the possible combinations of sequences taught by Horsburgh, Mori, or Cohen, Applicants’ particularly claimed sequences flanking a non-essential gene. None of the cited references teach or suggest inserting a BAC sequence into a flanking region of ORF 13. The cited references, alone or in combination fail to conceive of the use of Applicants’ specified flanking gene region(s) of an Oka strain for insertion of BAC vector sequences and production of an attenuated recombinant live varicella virus and vaccine thereof, having the advantageous effects demonstrated by Applicants’ claimed subject matter. Applicants’ claims are novel and non-obvious.

Applicants respectfully request reconsideration and withdrawal of this rejection.

## **V. DOUBLE PATENTING**

Claims 1, 8-10 and 12-18 remain provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 4, 11-17, 24 and 25 of co-pending Application No. 12/094,757.

Applicants again respectfully request that this provisional obviousness-type double-patenting rejection be held in abeyance until patentable subject matter is found in one of the co-pending applications, or until the other rejections in the present case are overcome and the claims of this case are otherwise in condition for allowance.

Again, the rejection is provisional because the claims of the cited applications have not been patented. It is improper for the Examiner to maintain a provisional obviousness-type double-patenting rejection based on claims that have not been allowed or issued in a patent. Until patentable subject matter is found in the applications not yet granted and serving as the basis of this provisional rejection, the claims of the instant application should be considered on their merits.

Thus, Applicants again respectfully request withdrawal of this provisional obviousness-type double-patenting rejection, and request that the claims of the instant application be considered on their merits.

Applicants reserve the right to file a terminal disclaimer in the event that it is deemed necessary in a later stage of prosecution.

#### **VIII. CONCLUSION**

In view of the foregoing, Applicants submit that the pending claims are in condition for Allowance. A Notice of Allowance is respectfully requested.

No fees, beyond the fee for a two-month extension of time, are believed to be due in connection with this Amendment. However, the Commissioner is authorized to charge any additional fees that may be required, or credit any overpayment, to King & Spalding LLP Deposit Account No. 50-4616.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 590-1932.

Respectfully submitted,  
KING & SPALDING LLP

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